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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,619	10/21/2002	Kojiro Takahashi	TAKAHASHI30	8322

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,619

Applicant(s)

TAKAHASHI ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of Claims

Claims 1-8 have been canceled in the amendment of 6/5/03.

Claims 9-12 have been added and are pending in the application.

Specification

The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of **50 to 150 words**. ***It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.*** The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The objection to the disclosure is withdrawn in view of the amendments to the specification correcting said errors.

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Claim Rejections - 35 USC § 101

The rejection of claim 8 under 35 U.S.C. 101 is moot with the cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action and reiterated below.

The specification fails to provide a written description for the different methods of making different nucleic acid compounds i.e., cDNA, gDNA, ss gDNA library. The specification provides a general description of an apparatus which contains these immobilized nucleic acids. It is not apparent from this disclosure the kind, if any, of even a single cDNA, gDNA, ss gDNA library that has been made utilizing the methods as claimed

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or disclosed. [The crux of the invention apparently resides in an apparatus that produces an immobilized nucleic acid.]

Furthermore, newly added claims 9-12 drawn to a continuous method for construction of a cDNA library with the recited steps is not described or supported in the as-filed specification. The original description does not disclose what constitute a continuous method for making the cDNA or gDNA or ssDNA or the steps of said continuous method for making the different DNAs.

Response to Arguments

Applicants argue that with the cancellation of claims 1-6 this rejection no longer applies. In response, even with the cancellation of claims 1-6, the rejection is maintained since the claims are drawn to nearly the same subject matter as claims 1-6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

New claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Claim 9 is indefinite as it is not clear what constitute a "continuous" method for constructing a cDNA library. It is not apparent from the body of the claim how such continuous method is made or achieved. The preamble is inconsistent with the body of the claim. The preamble recites for a continuous method while the body recites for obtaining a desired number of replicate. The claimed steps are confusing, as there appear to be a lack of nexus among the steps, especially since the specification does not recite for said process steps. "The" modified first support in step b lacks antecedent basis from the preceding step a. It is not clear how the first support is modified. The term "first" is a relative term which renders the claim indefinite. The term "first" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of inconsistent language "total RNA", "mRNA containing solution" provide for confusion and ambiguity.

B. Claim 10 is indefinite as the process steps do not seem to correlate with one another. It is not clear within the claimed context, a "perfect sense", especially in the absence of positive support in the specification for said term.

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C. Claim 12 is unclear as to the step and means by which the support "has been previously chemically modified".

Double Patenting

Claims 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,489,111 ('111 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the last Office action.

Response to Arguments

Applicants urge that method of the present invention relates to a continuous method for constructing a DNA library as shown in the flowchart of Fig. 3 and Fig. 5. Takahashi et al is argued not to disclose a continuous process. It is not clear within the context of the Figure how this is a continuous process. Although Takahashi does not disclose a flowchart for the process that makes the alleged continuous process, however, this does not indicate that it is not a continuous process. The steps of immobilization and separation are similarly disclosed by Takahashi.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 9-12 are rejected under 35 USC 102(e) as being anticipated by Takahishi et al (US PAT.NO. 6,489,111) for reasons set forth in the last Office action.

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Response to Arguments

Applicants argue that Takahishi does not recite for a continuous process for producing DNA libraries rather, a disparate process. In response, the process of Takashi would inherently be considered a continuous process. Claim 13 of Takahashi employs a computer control process which would presuppose a continuous operation of the process.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Schena et al (PNAS, 1996) or Schmidt et al (US 6,225,077 (102e) for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the present invention includes delivering TE solution into a container by driving liquid feeding means. Neither Schena nor Schmidt is argued not to disclose a step in which a cleaning solution is added.

In response, applicants' argument is not commensurate in scope with the claims which do not recite said cleaning with TE. See the method step of Schena at page 10614, last paragraph which discloses the argued cleaning step.

No claim is allowed.

Conclusion

-----Applicant's amendment necessitated the new ground(s) of
rejection presented in this Office action. Accordingly, **THIS**

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ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
August 23, 2003
